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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,540	04/15/2004	Robert E. Dudley	04272918	8236

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MAYER BROWN LLP
P.O. BOX 2828
CHICAGO, IL 60690

EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,540	DUDLEY ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *31,38 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30, 32-37, 39-40, and 42-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-79 are currently pending in the application.

Applicant's election of ethanol as the C1-C4 ethanol and isopropyl myristate as the penetration enhancer in the reply filed on 03/06/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 31, 38, and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

Objections

The abstract of the disclosure is objected to because it contains legal phraseology such as "comprises" in line 2. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claim 7 is particularly vague and indefinite given that applicant is claiming a steady-state testosterone 24-hour pharmacokinetic profile approximating the profile shown in Fig. 1(c) (**in sentence 2 of claim 7**). Applicant is reminded that claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience. *Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted)*. For the foregoing reason, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claim.

As a result of the above inconsistencies, the aforementioned claim is unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the purpose of

compact prosecution, Examiner will construe that the stated steady-state set forth in the claim comprises solely a steady state testosterone 24-hour kinetic profile.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 27, 47, 59, and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (**see M.P.E.P 608.01 (k)**).

Claims 27, 47, 59, and 73 are particularly vague and indefinite given that applicant is claiming testosterone "derivatives" (**in sentence 2 of all claims**). Given that applicant did not particularly point out what compounds constitute "derivatives" of testosterone or what the term "derivative" encompassed, one of ordinary skill in the art would not be able to fully ascertain the metes and bounds of the aforementioned claims.

As a result of the above inconsistencies, the aforementioned claims are unable to be examined as disclosed given that the scope of the claimed subject matter would not be able to be determined by one of ordinary skill in the art. However, for the purpose of compact prosecution, Examiner will construe that the stated species set forth in the claims comprise solely enantiomer, racemic mixture, a base, or a salt of testosterone.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58 and 61-62 of copending Application No. 11/911446 (hereinafter Dudley US Patent Application No. '446). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating hypogonadism in a subject comprising applying a hydroalcoholic gel containing testosterone to the skin of said subject in an amount effective to treat the hypogonadism. The claimed invention and co-pending application Dudley '446 are rendered obvious over another as the claimed invention teaches a method of treating hypogonadism to a subpopulation of male subjects comprising applying hydroalcoholic gel containing testosterone to the skin of the male subject whereas Dudley '446 teaches a method of preventing or alleviating the symptoms of testosterone deficiency (i.e. hypogonadism) in a broad population comprising mammalian subjects comprising administering testosterone enanthate and/or undecanoate solubilized in two or more lipid components. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No.11/911446.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 21-26, 28-30, 32-37, 39-40, 42-46, and 48-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, and 7-10 of copending Application No. 12/052337 (hereinafter Dudley US Patent Application No. '337). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating hypogonadism in a subject comprising applying a hydroalcoholic gel containing testosterone to the skin of said subject in an amount effective to treat the hypogonadism. The claimed invention and co-pending application Dudley '337 are rendered obvious over another as the claimed invention teaches a method of treating hypogonadism to a subpopulation of male subjects comprising applying hydroalcoholic gel containing testosterone to the skin of the male subject whereas Dudley '337 teaches a method of treating hypogonadism to a subpopulation of adolescent boys comprising administering a pharmaceutical composition in the form of a hydroalcoholic gel containing testosterone to said adolescent boy. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No.12/052337.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 8, 22-30, 32-33, 35-37, 39-40, 42-49, and 52-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-42, 44, 58-62, and 64-73 of copending Application No. 10/867445 (hereinafter Dudley US Patent Application No. '445). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating hypogonadism in a subject comprising applying a hydroalcoholic gel containing testosterone to the skin of said subject in an amount effective to treat the hypogonadism. The claimed invention and co-pending application Dudley '445 are rendered obvious over another as the claimed invention teaches a method of treating hypogonadism in a male subject comprising applying a composition formulated as a hydroalcoholic gel containing testosterone to the skin of the male subject whereas Dudley '445 teaches a method of treating hypogonadism in a male subject comprising administering a pharmaceutical composition to the skin of the subject, wherein the composition comprises 0.1%-10 testosterone, an alcohol, a penetration enhancer and a gelling agent. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No.10/867445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-30, 32-37, 39-40, and 42-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30, 32-37, 39-40, and 42-79 of copending Application No. 10/828678 (hereinafter Dudley US Patent Application No. '678). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating hypogonadism in a subject comprising applying a hydroalcoholic gel containing testosterone to the skin of said subject in an amount effective to treat the hypogonadism. The claimed invention and co-pending application Dudley '678 are rendered obvious over another as the claimed invention teaches a method of treating hypogonadism in a male subject comprising applying a hydroalcoholic gel containing testosterone to the skin of the male subject whereas Dudley '678 teaches a method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising applying a hydroalcoholic gel comprising testosterone. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No.10/828678.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al. (J. of Clin. Endo. and Met. August 18, 2000, Vol. 35, No. 8, pgs. 2839-2853, cited by applicant and filed on an IDS 1449).

Wang et al. teaches the use of a transdermal testosterone (T) gel (i.e. Androgel) in the treatment of hypogonadal men (instant claim 1; see abstract). The T gel provided dose proportionality increases in serum T levels to the normal adult range (instant claim 5; see abstract). Wang et al. further teaches that administration of 1% T containing 5 or 10 g of T for 180 days (instant claims 2-4) improved mean muscle strength in the leg and this necessarily reads on the limitation of claims 10-11 given that the hips constitute the upper part of the leg and uses the bone for movement (see abstract and pg. 2840, right col. T gel and patch section and Study Design section for days of administration; pg. 2844, right col.). The lean body mass was also found to be increased followed by a decrease in fat percentage, as well as sexual function (i.e. libido) including full erection, mood and muscle strength (instant claims 12-13 and 15-19; see abstract and pg. 2843-2846). The study of Wang et al. further demonstrates that the T gel formulation can rapidly increase serum T levels into the normal range as well as increased dihydrotestosterone serum concentration and steady state T serum pharmacokinetics

(instant claims 6-7 and 9; see pg. 2840, left col. paragraph 2 pg. 2842 and table 1). In addition, Wang et al. teaches that application of the T-gel resulted in serum T levels within the normal range of 10.4-34.7 nmol (i.e. 300-1000 ng/dL; instant claims 8 and 21, see pg. 2840, right col., Study Design section). Moreover, the T gel showed low skin irritation due to the open system and lower concentration alcohol in the T-gel formulation and suggests its use due to higher patient compliance (instant claim 20; see abstract and pg. 2840, left col. paragraph 2 see pg. 2852, left col., last paragraph).

Accordingly, the teachings of Wang et al. anticipate claims 1-21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 22-30, 32-37, 39-40, and 42-64 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wang et al. (J. of Clin. Endo. and Met. August 18, 2000, Vol. 35, No. 8, pgs. 2839-2853, previously cited by applicant and filed on an IDS 1449) as applied to claims 1-21 above in view of Androgel Data Sheet (Prescribing Information, as of August 18, 2000, pgs.1-11).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Wang et al. reference is as discussed above and incorporated by reference herein. However, Wang et al. does not teach what is included in Androgel including the concentrations of inactive ingredients or the concentration of alcohol.

Androgel Prescribing Information teaches that Androgel contains about 1% testosterone and is used for androgen replacement therapy males for conditions associated with hypogonadism (instant claims 1, 45-49 and 56-59; see pg. 1, left col.). It is available for topical use in a pump which administers 1.25 g T dose per pump or in 2.5 packet or 5 g packet (instant claims 53-55, see pg. 1, left col. and pg. 3, section 3). Importantly, Androgel Prescribing Information Sheet teaches that the T gel contains T as a white crystalline powder (i.e. salt form; instant claims 27, 47, 59), Carbomer 980 (i.e. polyacrylic acid), ethanol as the lower alcohol at 67% concentration (instant claims 23-26 and 64), isopropyl myristate (i.e. penetration enhancer), purified water, and

sodium hydroxide (instant claims 22, 28, 32, 34-37, 42, 50-52, 62; see pg. 7, Section 11, Description).

While Androgel Prescribing Information Sheet does not disclose the exact percentages of water, isopropyl myristate (i.e. penetration enhancer), or that of Carbomer 980 (i.e. polyacrylic acid, gelling agent), it is however well within the purview of the skilled artisan at the time of the invention to adjust the concentration and range of the penetration enhancer and gelling agent in the composition during the course of routine experimentation so as to obtain the desirable type of gel.

Moreover, it is generally noted that differences in concentrations or percentages do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or percentage is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or percentages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of percentages or ranges is the optimum combination of percentages.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize Androgel for treating hypogonadism since Androgel has been shown to be effective and less skin irritating as taught by Wang et al. Given that Wang

et al. teaches a method of treating hypogonadism using T gel Androgel effective in increasing serum T levels, and Androgel Prescribing Information teaches that Androgel additionally contains penetration enhancers, alcohol, gelling agent and water, one of ordinary skill would have been motivated to utilize Androgel as taught by Wang et al. with the reasonable expectation of providing a method that is effective at increasing serum testosterone levels with a low skin irritant composition.

Claims 65-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (J. of Clin. Endo. and Met. August 18, 2000, Vol. 35, No. 8, pgs. 2839-2853, previously cited by applicant and filed on an IDS 1449) as applied to claims 1-21 above in view of Androgel Data Sheet (Prescribing Information, as of August 18, 2000, pgs.1-11) as applied to claims 1, 22-30, 32-37, 39-40, and 42-64 above and in further view of Miller (U.S. 3,913,789).

The Wang and Androgel references are as discussed above and incorporated by reference herein. However, Wang and Androgel do not address the foil packet with an inner and outer surface with a polyethylene liner.

Miller teaches a well-sealed container comprising two layers of sheet materials of similar size and shape which form opposed walls and which are sealed together along marginal areas which provides good flow ability (see abstract, col. 2. lines 21-25 and col. 2, lines 51-51). Miller further teaches that the sheet material is determined by the

nature of the contents and can be a metal foil such as aluminum or tin and inside can include polyethylene given that polyethylene film is well adapted to use for containing a wide variety of fluids (see col. 1, lines 46-58; instant claims 64 and 79).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the foil packet of Miller given that Miller teaches a foil packet with good flow ability for fluid-like compositions. Given that Miller teaches a foil packet with polyethylene liner with good flow ability, one of ordinary skill would have been motivated to utilize the foil packet of Miller with the reasonable expectation of providing a foil packet-containing composition for the treatment of hypogonadism that is efficient in dispensing the T gel.

Claim Rejections - 35 USC § 102

Claims 1, 16, 18-20, 22-27, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Mak et al. (WO 99/24041, previously cited by applicant and filed on an IDS 1449) as evidenced by Merck Index (Merck Index, Male Hypogonadism, pgs.1-6).

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Mak et al. teaches a method of treating testosterone deficiency (instant claim 1; pg. 3, lines 16-17) comprising administering an active agent such as testosterone or

testosterone derivative and a penetration-enhancing system containing oleic acid; a C1-C4 alcohol; a glycol; optionally comprising a gelling agent, carbopol (i.e. polyacrylic acid), and optionally formulated as a gel (see pg 2 lines 30-32, pg. 3, lines 1-5). Mak et al. further teaches that the composition reduces skin irritation and increases drug permeability due to the presence of penetrating enhancers and suggests the use of a mixture of enhancers (instant claim 20; see pg. 2, lines 2-5). The composition of MaK et al. contains testosterone is the active agent that can be used in a concentration of 0.1-10%, 0.1-5%, 1-2% (instant claims 24-27), C1-C4 alcohol such as ethanol in an amount of 5-55%, 10-40%, or 25-35%, oleic acid, glycol, gelling agent or polyacrylic acid in a range of 1-10%, 1-5% or 1-3% (instant claims 32-33). Mak et al. further teaches that his composition is also effective in promoting increased muscle size which necessarily leads to lower body fat and a change in body composition (instant claims 16 and 18-19) and administered to humans which necessarily includes male humans (i.e. male subjects; see pg. 7, lines 25-27 and pg. 8, lines 1-3, and 20-21). Mak et al. also exemplify the formulation in table 2 wherein formula 545 which contains, 2% T, 36.6% propylene glycol, 15% ethanol, 15% isopropyl alcohol, 1% oleic acid, 0.6% Carbopol 1342, 0.4% TEA and 29.4% water, possesses a low skin irritation score (instant claims 22-23; see pg.. 11, table 2, formula 545 and pg. 18, example 9).

Merck Index has been provided to demonstrate that hypogonadism is defined as testosterone deficiency and thus Mak et al. necessarily teaches a method of treating hypogonadism (see pg. 1, top paragraph).

Accordingly, the teachings of Mak et al. anticipate claims 1, 16, 18-20, 22-27, and 32-33.

Claims 28-30, 35-37, 39-40, 42-50, and 52-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (WO 99/24041, previously cited by applicant and filed on an IDS 1449) as evidenced by Merck Index (Merck Index, Male Hypogonadism, pgs.1-6) as applied to claims 1, 16, 18-20, 22-27, and 32-33 above and in further view of Thornfeldt et al. (U.S. 5,760,096).

The Mak et al. reference is as discussed above and incorporated by reference herein. However, Mak et al. does not teach isopropyl myristate as the penetration enhancer or the particular percentage of isopropyl myristate...

Thornfeldt et al. teaches composition containing combinations of penetration enhancers including branched chain esters of fatty acids (see abstract). Thornfeldt et al. further teaches that incorporating the particular enhancers will help significantly in increasing the permeability of the drug while minimizing irritation of the skin (see col. 1, lines 49-54). Importantly, Thornfeldt et al. teaches isopropyl myristate as preferred branched chain esters to add to his composition in 0.05-50% by weight of 0.5-20% by weight (see col. 2, lines 41-43 and 50-53 and col. 4, lines 52-54).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add isopropyl myristate into the method of Mak et al. since Thornsfeldt et al. teaches that combination of enhancers entailing isopropyl myristate

help to increase drug permeability and lower skin irritation. Given that Thornfeldt et al. teaches inclusion of isopropyl myristate in composition for increased drug permeability and low skin irritation, one of ordinary skill would have been motivated to add isopropyl myristate into the composition of Mak et al. with the reasonable expectation of providing a method that is effective at increasing serum testosterone levels with a low skin irritant composition.

Claims 65-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (WO 99/24041, previously cited by applicant and filed on an IDS 1449) as evidenced by Merck Index (Merck Index, pg.1) as applied to claims 1, 16, 18-20, 22-27, and 32-33 above in view of Thornfeldt et al. (U.S. 5,760,096) as applied to claims 28-30, 35-37, 39-40, 42-50, and 52-64 above and in further view of Miller (U.S. 3,913,789).

The Mak, Merck Index, and Thornfeldt references are as discussed above and incorporated by reference herein. However, Mak, Merck Index, and Thornfeldt do not address the foil packet with an inner and outer surface with a polyethylene liner.

Miller teaches a well-sealed container comprising two layers of sheet materials of similar size and shape which form opposed walls and which are sealed together along marginal areas which provides good flow ability (see abstract, col. 2. lines 21-25 and col. 2, lines 51-51). Miller further teaches that the sheet material is determined by the

nature of the contents and can be a metal foil such as aluminum or tin and inside can include polyethylene given that polyethylene film is well adapted to use for containing a wide variety of fluids (see col. 1, lines 46-58; instant claims 64 and 79).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the foil packet of Miller given that Miller teaches a foil packet with good flow ability for fluid-like compositions. Given that Miller teaches a foil packet with polyethylene liner with good flow ability, one of ordinary skill would have been motivated to utilize the foil packet of Miller with the reasonable expectation of providing a foil packet-containing composition for the treatment of hypogonadism that is efficient in dispensing the T gel.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

06/06/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617